codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 4 **CX/MH 04/10/4**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON MEAT HYGIENE
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PROPOSED DRAFT ANNEX ON RISK-BASED[1] POST-MORTEM EXAMINATION PROCEDURES FOR MEAT

Governments and interested international organisations in observer status with Codex are invited to comment on the attached proposed draft annex on risk-based post-mortem examination procedures for meat. Comments should be sent to:

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with a copy to the Secretary, Codex Alimentarius Commission, Viale delle Terme di Caracalla, 00100 Rome, Italy **not later than 19 December 2003.**

BACKGROUD

The 9th Session of the Codex Committee on Meat and Poulty Hygiene appended the proposed draft Annex on Risk-Based Post-Mortem Examination Procedures for Meat to its report for comments[2]. The Committee agreed that a drafting group under the direction of New Zealand, would prepare a revised version of the Annex (see Appendix I to this document) on the basis of the text attached to its report, the discussions and written comments submitted at that meeting and written comments received in response to CL 2003/10-MPH, part B (see Appendix II to this document) for circulation, additional comments and further consideration at its next meeting. [3]

Governments and interested international organizations in observer status with Codex are invited to comment at Step 3 on the attached proposed Annex on Microbiological Verification of Process Control of Meat Hygiene, as directed above.

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1 The term "risk-based" can be applied to a food safety measure, a group of measures, a food safety programme or a food safety system. For the purposes of the CCMH, "risk-based" is defined as "containing performance criteria and/or process criteria developed according to risk analysis principles"

2 Comments were requested under CL 2003/10-MPH, part B

3 ALINORM 03/16A paras. 90-91 and Appendix IV

Appendix I

PROPOSED DRAFT ANNEX ON RISK-BASED[4] POST-MORTEM EXAMINATION PROCEDURES FOR MEAT

1. Introduction

1. Post-mortem meat examination procedures are a set of food hygiene measures that are unique to the production of meat. Such procedures are regarded as a component of overall process control, which is defined as "all conditions and measures applied during the production process that are necessary to achieve safety and suitability of meat"[5].

2. The General Principles of Food Hygiene state that "in deciding whether a [food control] requirement is necessary or appropriate, an assessment of the risk should be made, preferably within the framework of the HACCP approach" [6]. Traditional post-mortem meat examination procedures are often complex, labour-intensive, undifferentiated for different classes of slaughtered livestock, and poorly evaluated in terms of their relative contribution to reducing food-borne risks to public health. For these reasons, competent authorities in a number of countries are carrying out investigations into the scientific basis of current procedures[7].

3. Although the principles and guidelines presented in this Annex can be adapted to evaluation of post-mortem examination procedures for determining the suitability of meat, such methodology is not developed.

2. Objectives of risk-based post-mortem examination procedures for meat

4. A risk-based approach to post-mortem examination for meat can achieve the following objectives:

- Determination of the level of consumer protection provided by specified post-mortem examination procedures;
- Relative measurement of the contribution of post-mortem examination to the overall level of control of hazards in meat (and risks to consumers), thereby allowing risk managers to allocate meat hygiene resources proportionate to their greatest benefit in preventing meat-borne risks;
- Comparison of the effectiveness of different examination procedures applied for the same purpose and in the same context;
- Provision of information that allows appropriate evaluation of different risk management options e.g. regionalisation of examination programmes, feasibility and comparative costs of different post-mortem examination procedures, potential for cross-contamination;
- Full integration of post-mortem examination procedures into a "production-to-consumption" meat hygiene programme.

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4 The term "risk-based" can be applied to a food safety measure, a group of measures, a food safety programme or a food safety system. For the purposes of the CCMH, "risk-based" is defined as "containing performance criteria and/or process criteria developed according to risk analysis principles"

5 Proposed Draft Code of Hygienic Practice for Fresh Meat (CX/MPH 3/4)

6 General Principles of Food Hygiene CAC/RCP 1-1969, Rev. 3 (1997), Amended 1999

7 Competent authorities have different approaches to defining the respective roles of industry and competent authority personnel in delivering meat hygiene activities, and this issue is not covered in this Annex

3. Risk analysis

3.1. Risk management framework

5. Development and implementation of risk-based post-mortem examination procedures should utilise a risk management framework[8]. The four components are: preliminary risk management activities, evaluation of risk management options, implementation, and monitoring and review. All components require effective risk communication among risk assessors, risk managers and other interested parties as necessary. Utilisation of a risk management framework is the subject of on-going work within the Codex system, and is described in a number of Codex documents[9].

3.2. Risk assessment

6. If required, a risk assessment is commissioned during preliminary risk management activities. A risk assessment consists of four steps: hazard identification, hazard characterisation, exposure assessment, and risk characterisation. The output of this process should be qualitatively integrated with all other factors relating to post-mortem meat examination to make risk management decisions on appropriate procedures for control of hazards.

7. In the ideal situation, risk estimates will be quantified in terms of risks to human health, and risk management decisions on an appropriate level of protection (ALOP) will dictate the nature and intensity of the post-mortem examination procedures to be applied. However, risk assessment of microbiological hazards in meat is currently limited by a lack of quantitative risk assessment models. Nevertheless, appropriate assembly of scientific information and qualitative risk characterisation as to the probable impacts on human health can provide an objective basis for decision-making. In the latter case, risk management decisions will revolve around the acceptability of the likely human health impact of differences in hazard levels brought about by different examination procedures.

4. General principles for development of risk-based post-mortem meat examination procedures

i. Risk-based post-mortem examination procedures should be derived from the application of risk analysis principles.

ii. Development of risk-based post-mortem examination procedures should:

- Involve application of a risk management framework to the greatest extent appropriate and practicable;
- Include quantitative risk assessment where appropriate and practicable;
- Take into account all relevant information available from the food chain.

iii. Examination procedures should be evaluated for application within a specific context e.g. species and class of slaughtered animal, defined geographical region, defined animal husbandry system.

iv. Where different examination procedures that have the same purpose and context are being evaluated:

- An objective basis for comparison of the level of control of hazards associated with these procedures, should be established;
- The efficacy of each examination procedure in detecting abnormalities affecting the safety of meat should be taken into account;
- Other risk management factors should be taken into account as appropriate e.g. potential for inadvertent cross-contamination, feasibility, and practicality.

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8 Proposed Draft Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius. ALINORM 03/33 Appendix II. FAO Rome 2002

9 Risk Analysis Policies of the Codex Alimentarius Commission. Twenty-fourth Session of the CAC. ALINORM 01/9. FAO 2001

v. Where needed, representative and sufficiently large field trials should be undertaken to determine the performance attributes of specified examination procedures e.g. sensitivity, specificity, and non-detection rates for grossly-detectable abnormalities.

vi. Where appropriate, laboratory investigations should be designed to detect the range of hazards of possible public health importance that have been described in hazard identification.

vii. Routine application of post-mortem examination procedures should not inadvertently increase cross-contamination with microbiological hazards.

viii. Irrespective of examination delivery systems, the competent authority should be responsible for defining the role of personnel involved in post-mortem examination procedures, and verifying that any performance criteria expressed as regulatory guidelines or standards are met.

5. Guidelines for the development of risk-based post-mortem examination procedures

5.1. Identification of the Meat Hygiene Issues

8. An hazard identification process should be undertaken to determine the likely range of hazards of public health significance that may be present in grossly-detectable abnormalities in target tissues. Following this, field trials should be undertaken to determine the performance attributes of specified examination procedures relative to the hazards that may be present.

5.2. Field trials

9. Once the likely range of hazards has been established, field trials may be an appropriate means to establish the prevalence of these hazards in the animal population, the potential exposure of consumers to these hazards and the potential impact of different examination procedures on this exposure. Field trials should be carried out under competent authority supervision and employing competent personnel. The number of animals examined by the inspection procedures under evaluation should give a statistically valid estimate of the detection rate of gross abnormalities achieved by specific post-mortem examination procedures.

10. Sampling plans should be representative of the slaughter population, and cater for known biological variation in respect of the type and prevalence of grossly-detectable abnormalities e.g. influence of animal age, geographical region, farming type and season. Different trial designs may be employed, depending on the prevalence of grossly-detectable abnormalities in the slaughter population, and the logistics of detailed examination.

11. Where different post-mortem examination procedures are being compared: all procedures should be applied to the same animals, each examination station should be designed to provide independent results, and the trial should include enough samples so as to allow definite conclusions as to the consequences of changing examination procedures. The possibility of target tissues acting as “indicators” for detection of gross abnormalities in other tissues and/or disposition of other tissues should be included in the design of field trials. Detailed recording of trial results is necessary, including appropriate pathological descriptions of all abnormalities detected.

12. Laboratory investigations e.g. microbiological examination and histology, should be designed to identify the range of hazards of possible public health importance that have been identified in the hazard identification process. A representative number and range of samples should be taken from grossly-detectable abnormalities, so as to confirm the outcome of the hazard identification process and provide as much information as possible on the prevalence (and concentration) of hazards in target tissue. Trial design should include representative surveying of the prevalence (and concentration) of hazards in target tissues that are grossly normal, so as to provide a comparison with the prevalence (and concentration) of hazards in those tissues that are grossly abnormal.

5.3 Performance attributes

13. An understanding of the level of consumer protection that is achieved by particular examination procedures requires knowledge of the level of control of hazards that is attained in meat. These would be reflected in microbiological performance criteria and/or process criteria[10] where these have been defined. Performance attributes[11] for post-mortem examination procedures should achieve these microbiological performance criteria and/or process criteria.

14. The performance attributes of the examination procedures e.g. visual examination, palpation, and/or incision, should be determined within appropriate statistical limits established by the competent authority. The intended end-use of the target tissues has an important influence on the development of risk-based post-mortem examination procedures.

15. The sensitivity of a post-mortem examination procedure is the probability of correctly identifying gross abnormalities that are likely to contain public health hazards. An examination procedure with a high sensitivity will result in a low non-detection rate for abnormalities containing hazards i.e. few false negatives.

16. The specificity of an examination procedure is the probability of correctly identifying gross abnormalities that do not contain public health hazards. An examination procedure with a high specificity will result in a low detection rate for abnormalities that do not contain hazards i.e. few false positives.

17. The true prevalence of grossly-detectable abnormalities affecting the tissues subject to post-mortem examination ("gold standard") should be determined as part of the above process.

5.4 Risk management decisions

18. Risk management decisions on the acceptability or otherwise of specified post-mortem examination procedures will generally be based on the worst case of non-detection of gross abnormalities included in an appropriate statistical confidence interval. Decisions should take into account the comparative public health risks associated with:

    - The prevalence (and concentration) of hazards in target tissues that are grossly abnormal;
    - The prevalence (and concentration) of hazards in target tissues that are grossly normal;
    - The overall prevalence (and concentration) of hazards being transmitted by all pathways throughout the production of meat.

19. In the general case, new or alternative examination procedures should provide a level of consumer protection that is at least equivalent to that provided by existing procedures, unless there are strong mitigating factors that may influence a different risk management choice e.g. unacceptable introduction of new hazards, undue risks from occupational exposure.

20. Required regulatory outcomes for post-mortem examination may include performance attributes expressed as limits on non-detection rates for particular abnormalities. Those performance attributes may be derived quantitatively from risk assessment models, or qualitatively from baseline surveys of current performance.

21. Where detailed information on the health status of slaughtered animals is available from primary production, risk-based post-mortem examination procedures may be modified on a lot-by-lot basis.

22. The competent authority should regularly analyse results of post-mortem examination at both the establishment and national level, and provide appropriate feedback to establishments and other interested parties on the performance of risk-based post-mortem examination procedures.

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[10] Microbiological performance criteria and process criteria are as defined by CCFH Working Group on "Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management"

[11] A working definition of performance attribute is: a quantitative parameter derived from estimates of sensitivity and/or specificity of a meat examination procedure.

23. The competent authority may change presentation requirements and the sequence of examination procedures as a result of scientific evaluation of different post-mortem examination procedures, and allow introduction of new examination tools e.g. mirrors. Alternative technologies for detecting abnormalities e.g. tissue imaging, should be acceptable to the competent authority if validated as being as effective as current procedures.

Appendix I

Comments in response to CL 2003/10-MPH, Part B

Comments from: Australia, Canada, Egypt, Thailand, United States, European Community, OIE

These comments were considered with discussion, written comments submitted at the 9th Session[12]

GENERAL

AUSTRALIA

Australia appreciates the opportunity to comment on the draft Annex and extends its thanks to the Codex Consultant and the Government of New Zealand for the elaboration of the draft text.

CANADA

Canada compliments New Zealand for its work in leading the Drafting Group to revise the *Proposed Draft Annex on Risk Based Post-Mortem Examination Procedures for Meat*. As the document reflects Canada's interventions at the 9th Session (February 2003) of the Codex Committee on Meat Hygiene, we offer these additional comments to further clarify our interventions and for consideration as appropriate.

EGYPT

EOS supports the draft proposal under item 5.5. (Risk Management Decisions) as in Table 1 (page 6) and Table 2 (page 7) with special reference to the column of Codex example.

UNITED STATES

Ante- and Post-mortem systems should allow examinations to be performed by a competent person with verification by official inspectors.

The United States appreciates the work of New Zealand in developing the Proposed Draft Annex on Risk-Based Post-Mortem Examination Procedures. The United States support the concept outlined in the draft document. References to performance parameters should be changed to performance criteria, or eliminated from the conceptual basis of this document.

EUROPEAN COMMUNITY[13]

The European Community (EC) would like to thank New Zealand for the work involved in developing this document. The EC would like to make the following comments.

The European Community supports the development of an Annex II to the proposed draft Code of Hygienic Practice for Fresh Meat, on Risk-based post-mortem inspection procedures for fresh meat. However, the proposed document is not very clear as regards structure and content.

OIE

In general the OIE is concerned with the approach taken in the current text could have significant negative consequences in particular to developing countries. It fails to identify the importance of the interdependence between meat hygiene and animal health in ante- and post-mortem procedures. As drafted this generic non-specific guidelines make no reference to the current meat inspection and international certification systems available in most countries.

Furthermore, this text tends to focus primarily on recommendations to be used internally at national level rather than providing guidance for the safety of meat in international trade.

The use of the term "examination" rather than "inspection" for ante-mortem and post-mortem procedures will create problems for Member Countries fulfilling their SPS obligations regarding export certification for many zoonoses, as it is in conflict with the already adopted standards of the OIE.

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12 CX/MPH 03/5 Add 1 and Conference Room Documents 1, 3, and 4.

13 Comments repeated in Plenary and CRDs.

TITLE

EUROPEAN COMMUNITY

The issue of 'ante-mortem inspection' is not dealt with in the document. The title should therefore not mention 'ante-mortem inspection'.

The terminology of the title should be put in line with the terminology of the Code. For instance, the Code proposes the use of the words 'ante-mortem *examination*'.

1. INTRODUCTION

PARAGRAPH 2 BIS

OIE

Whether or not competent authorities have jurisdiction over both meat hygiene and animal health, ante-mortem inspection and tests should be integrated so as to achieve public health and animal health objectives in the most cost effective and efficient manner. In such cases, all aspects of ante-mortem and post-mortem inspections should be science-based and be tailored to the relevant risks.

The OIE disagrees with the decision to remove reference to ante-mortem inspections being conducted under the supervision of an official veterinarian. OIE also disagrees with the change of the term ante-mortem inspection to examination, as OIE Member Countries have adopted the term "inspection" throughout the Code and base their certifications on that. If examination means 'detailed inspection', and if it is supposed to be "a stronger word than inspection", then it needs to be defined regarding obligations in international certificates.

The OIE does not understand why it was decided that this draft would not include ante-mortem procedures, while reference to these is made in several segments of this draft, such as several paragraphs of Section 6, on presentation of animals for slaughter. For the same reason, OIE is not in agreement with the title of the draft being limited to post-mortem procedures. Ante-mortem procedures as well as on-farm inspections continue to be important elements of a national surveillance program for public as well as animal health.

The OIE consider slaughterhouses as key points of epidemiological surveillance of non zoonotic animal diseases and zoonoses. The example of discovering the first FMD outbreak in UK in 2001 in an abattoir of pigs is interesting. The OIE fully agree with a certain reduction of veterinary inspection for animal batches coming with favorable farmer data, but this system is not yet implemented in more than 120 Member Countries of the OIE.

PARAGRAPH 3

EUROPEAN COMMUNITY

The second sentence is not clear. It would appear that the aspect of suitability is not covered by the Annex. However, the European Community is of the opinion that post-mortem inspection procedures should in principle detect gross abnormalities irrespective of whether or not a public health hazard is involved.

2. OBJECTIVES OF RISK-BASED POST-MORTEM EXAMINATION PROCEDURES FOR MEAT

PARAGRAPH 4

THAILAND

Bullet 5 should be amended as follows:

- Full integration of effective post-mortem examination procedures into a "production-to-consumption" meat hygiene programme.

Rationale: To ensure that the risk-based post-mortem examination procedures should be effective through the food chain. We propose to add the term effective in the sentence.

EUROPEAN COMMUNITY

The introductory sentence of the paragraph speaks about *development* of post-mortem inspection procedures. However, paragraph 4 seems to deal more with the evaluation of post-mortem procedures and not with the development (this latter aspect is tackled in the subsequent paragraphs).

3. RISK ANALYSIS

CANADA

Canada notes that within this section there is an absence of risk communication. Therefore maybe it would be pertinent to include a paragraph on risk communication.

PARAGRAPH 8

CANADA

We recognise that performance and process criteria are still being defined. But we introduce the term performance attributes and we know that it is not defined anywhere, and think it may be a good idea to do so.

We note that Paragraph 8 includes two footnotes (7 and 8) which contain definitions for "performance criteria" and "process criteria". The definitions in the footnotes are not consisitent with the definitions in the Code of Hygienic Practice for Meat. The footnotes should be revised to be consistent with the Codex. In addition, the second sentence of this paragraph refers to "performance parameter" and should instead refer to "performance criterion".

Further to our comment regarding the need for a paragraph dealing with Risk Communication, Canada recommends inserting a new subsection 3.3 entitled Risk Communication and a new Paragraph 8 as follows:

> 3.3 Risk Communication
>
> 8. Clear, interactive and documented communication among risk assessors, risk managers and other interested parties should ensure the consideration of all information and opinions required for the development of effective risk-based post mortem examination procedures.

As a result, the subsection on "Performance and process criteria" which follows would have to be renumbered to subsection 3.4 and the subsequent paragraphs would need to be renumbered.

4. GENERAL PRINCIPLES FOR DEVELOPMENT OF RISK-BASED POST-MORTEM MEAT EXAMINATION PROCEDURES

BULLET POINT IV

AUSTRALIA

Second bullet point – should this refer to 'safety' of meat rather than 'suitability' or in fact should it cover both 'safety and suitability'.

CANADA

1st bullet point - Canada recommends that the objective basis for comparison deal with the level of risk to consumers rather than the level of control of hazards. It may be that, in many cases, the level of control of hazards is directly linked to consumer risk; however, in a risk based approach, comparison should be at the level of risk rather than hazard. Hence, the first bullet of Section 4. iv should read, "An objective basis for comparison of the level of control of risks associated with specific hazards should be established".

BULLET POINT VI

AUSTRALIA

Laboratory analyses might not be necessary in all instances to detect or confirm the identified hazards – visual or organoleptic confirmation of the examination findings might be sufficient. Should these by qualified by 'where appropriate, laboratory investigations …..'

THAILAND

We propose that the phrase 'abnormal and grossly-normal tissue' should be deleted because only abnormal tissue should be investigated in laboratory to detect the range of hazards of public health. The sentence should be amended as follows:

'Laboratory investigations ~~of abnormal and grossly-normal tissue~~ programme of meat should be designed to detect the range of hazards of possible public health importance that have been described in hazard identification.

5. GUIDELINES FOR THE DEVELOPMENT OF RISK-BASED POST-MORTEM EXAMINATION PROCEDURES

CANADA

Canada believes as a general statement that there is something missing between 5.1 and 5.2. The text in para 10 does not indicate what are being evaluated in field trials. As currently structured the whole section appears to provides some direction on two different procedures but does not take into account other possible objectives such as the establishment of or the assessment of performance against performance criteria. So we believe that this whole section would gain from being reordered. We have some proposed text that will be given later as they are extensive.

Section 5.4 the committee needs to look closely at how the terms sensitivity and specificity have been used in these paragraphs and Canada have comments have comments on how they should be used.

Section 5.2 Field Trials

Canada recommends that the title of this subsection be modified to put the field trials into the context of a risk based system, e.g. "Field trials to establish prevalence and impact of examination procedures". Canada also notes that paragraphs 87 and 88 of the report of the 9th Session of CCMH (Alinorm 03/16A) recommend major modifications to the content and order of paragraphs 10 through 17 to improve the readability of this document.

The following line should be inserted into Paragraph 10, as the first sentence: "*Once the likely range of hazards has been established, field trials may be an appropriate means to establish the prevalence of these hazards in the animal population, the potential exposure of consumers to these hazards and the impact of different examination procedures on this exposure.*

As per the report, paragraph 10 should then be followed by paragraphs 11 and 13, Section 5.3 and finally paragraph 12.

With respect to the use of the terms sensitivity and specificity, Canada recommends the following changes to current paragraphs 15 and 16:

> Paragraph 15 - The sensitivity of a post mortem examination procedure is the probability of correctly identifying a gross abnormality (which may contain public health hazards) in an affected carcass and hence correctly identifying the carcass as being affected by such an abnormality. An examination procedure with a high sensitivity will result in a low non-detection rate for these abnormalities in affected carcasses. *Foot Note: It should be stressed that it is the definition of the gross abnormality to be detected that establishes whether or not a health hazard exists, not the examination procedure.*

Paragraph 16 - The specificity of an examination procedure is the probability that a carcass is correctly identified as being affected by a specific gross abnormality (which may contain public health hazards). An examination procedure with a higher specificity will result in a lower rate of carcasses falsely identified as having such abnormality than an examination procedure with a lower specificity.

PARAGRAPH 9

AUSTRALIA

Australia would prefer to have field trials carried out under the supervision of the competent authority which might chose to utilise other professional expertise rather than a veterinarian, e.g. a food scientist with veterinary support.

EUROPEAN COMMUNITY

It is not clear why the hazard identification process should be only *empirical*. It might be appropriate to carry out specific scientific studies. In addition, the relation with paragraph 13 is unclear.

PARAGRAPH 10

AUSTRALIA

Australia suggests deletion of the reference to ("gold standard") in this paragraph to avoid the necessity of developing a definition or explanatory note on the meaning of the term.

UNITED STATES

The second sentence in paragraph 10 reads, " The number of animals examined by the procedures under evaluation should be sufficiently large so as to give an estimate of the true prevalence of gross abnormalities achieved by specific post-mortem examination procedures.

We recommend that "sufficiently large" in the second sentence be replaced with "established by statistical designed sampling plans."

EUROPEAN COMMUNITY

Field trials should not be carried out to give a reliable estimate of the true prevalence of gross abnormalities but rather to give an estimate of the detection rate of gross abnormalities achieved by specific post-mortem inspection procedures.

PARAGRAPH 11

THAILAND

We are of the opinion that the context in this paragraph is in detail. Therefore we propose to delete the phrase at the end of paragraph and the last sentence should read

"Different trial designs may be ……., the logistics of detailed ("gold standard") examination, ~~and the number of competent persons available.~~

PARAGRAPH 14

AUSTRALIA

Australia suggests changing to 'competent authority'.

UNITED STATES

The first sentence in paragraph 14 reads, "The performance attributes of the examination procedures (e.g., visual examinations, palpation, and/or incision) should be determined within appropriate statistical confidence limits."

It is unclear what is meant here by the term “appropriate statistical confidence limits. We support the identification of selection of the most appropriate examination procedure by evaluation of performance attributes using appropriate measures, including a statistical analysis of performance data.

We recommend clarification to read, “The performance attributes of the examination procedures (e.g., visual examinations, palpation, and/or incision) should be determined within appropriate statistical limits established by the competent authorities.”

EUROPEAN COMMUNITY

This should be Sub-Chapter 5.3 instead of 5.4.

PARAGRAPHS 15 AND 16

EUROPEAN COMMUNITY

The definitions of the words sensitivity and specificity are confusing, especially the relation with ‘public health hazards’. Considering the fact that post-mortem inspection procedures should detect gross abnormalities irrespective of whether or not a public health hazard is involved, these definitions seem inappropriate.

PARAGRAPH 19

EUROPEAN COMMUNITY

It is not clear what alternative inspection procedures and traditional procedures are. These terms should be clarified and defined.

PARAGRAPH 20

CANADA

Canada recommends removal of the word ″industry″ from the last sentence because there may be times when the parameter that is going to be measured may be an examination procedure that is being undertaken by a non-industry person, e.g., third party, government employee, etc. For example, the work of government inspectors is also subject to performance assessment (e.g., non-detection rates of disease "X"). Therefore, we believe that the word "industry" should be removed to broaden the statement.

PARAGRAPH 23

CANADA

Canada suggests that the last part of the last sentence be modified as follows: “if validated as being as effective as current procedures.” This allows for the comparison of all types of examination procedures, organoleptic or otherwise.

EXAMPLES

EUROPEAN COMMUNITY

The examples are not well presented and therefore not easy to understand. Their relevance for this exercise can be questioned.